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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/673,660	09/29/2003	William T. Donofrio	END-5029	2360
27777	7590	10/05/2005	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			ROY, ANURADHA	
			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 10/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/673,660

Applicant(s)

DONOFRIO ET AL.

Examiner

Anuradha Roy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date July 12, 2004.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

*DETAILED ACTION*

**Claim Rejections - 35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1-3, 6, 11-17, 19, & 20 rejected under 35 U.S.C. 102(b) as being anticipated by Hickie (US Patent No. 6,745,764).

Regarding claims 1, 14, & 16, Hickie discloses a conscious sedation system comprising: a) a controller (14) which generates a request for a predetermined hand motion response from a patient, which analyses at least a hand motion response made by the patient to the request to determine a level of sedation of the patient, and which generates a feedback signal (Column 7, lines 8-10) which is communicated to the patient; and b) a response testing apparatus (256, 264, & 266) including: a request assembly (256 & 264) which communicates to the patient the request generated by the controller of the conscious sedation system for a predetermined hand motion response from the patient; and a response assembly (256 & 254) which senses the hand motion response made by the patient to the request and which communicates the hand motion response to the controller which analyzes at least the hand motion response to determine a level of sedation of the patient.

With regards to claim 2, Hickie discloses a conscious sedation system, wherein a user and/or the controller determines a delivery schedule of a conscious- sedation drug to the patient based at least in part on the determined level of sedation of the patient (Column 7, lines 4-18).

Regarding claim 3, Hickle discloses a conscious sedation system, wherein the response assembly includes a handpiece (55), which sends a signal to the controller when the handpiece is moved.

Regarding claim 6, Hickle discloses a conscious sedation system, wherein the controller analyzes at least the position and/or orientation and/or changes therein of the handpiece to determine the level of sedation of the patient (Column 21, lines 19-44).

In regards to claims 11, 12, & 13, Hickle discloses a conscious sedation system, in which the predetermined hand motion response is the patient moving a hand toward another part of the body and the patient moving a hand to trace out a figure (Column 21, lines 33-44). Examiner is contending that the depression of the button as a linear traced figure. Furthermore, Hickle discloses a conscious sedation system, wherein the controller makes two requests, one of the two requests being for the patient to move a hand toward another part of the body and the other of the two requests being for the patient to move a hand to trace out a figure, wherein the controller at least analyzes the responses from the two requests to determine the level of sedation of the patient (Column 21, lines 21-30 & 33-41).

Regarding claim 15, Hickle discloses a conscious sedation system, wherein the controller changes the predetermined criteria between two requests and at least analyzes the responses from the two requests to determine the level of sedation of the patient (Column 21, lines 19-67).

Regarding claim 17, 19, & 20, Hickle discloses a response testing apparatus (256 & 254), wherein the response assembly senses at least one of a translation and a rotation of the hand of the patient (Column 21, lines 33-41) and includes a motion detector (Column 21, lines 33-38 & Column 35, lines 16-21) supportable by the hand of the patient, and wherein the assembly includes a touch pad (Column 21, lines 33-38) disposable proximate the hand of the patient.

### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4, 5, 7-10, & 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hickie in view of Foxlin (US Patent No. 2003/0023192).

Hickie discloses a conscious sedation system comprising: a) a controller (14) which generates a request for a predetermined hand motion response from a patient, which determines a level of sedation of the patient; and b) a response testing apparatus (256, 264, & 266) including: a request assembly (256 & 264) which communicates to the patient the request generated by the controller of the conscious sedation system for a predetermined hand motion response from the patient; and a response assembly (256 & 254) which senses the hand motion response made by the patient to the request and determines the level of sedation of the patient. Hickie does not, however, disclose a handpiece including accelerometers, specifically three mutually-orthogonal accelerometers, to analyze at least the position, the velocity, and the acceleration of the handpiece to determine the level of sedation of the patient. Furthermore, Hickie does not disclose a response assembly including a telemetry tracking system for tracking hand motion of the patient. Foxlin, however, discloses a handpiece (Figure 9), which includes three mutually orthogonal accelerometers (1311) to analyze at the least the position, the velocity, and acceleration of the handpiece. In addition to that, Foxlin also teaches the use of telemetry tracking system [0061]. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include three mutually orthogonal accelerometers and a telemetry tracking system to acquire a

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detailed analysis of the position, the velocity, and acceleration of the handpiece in order to enhance the determination of sedation level.

### Conclusion


The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Bennett (US Patent No. 5,195,531) and Tsutsumi et al. (US Patent No. 6,315,736) disclose a system in determining a level of consciousness in a patient. Townsend et al. (US Publication No. 2002/0170193), Foxlin (US Patent No. 6,786,877), and Foxlin (US Patent No. 6,361,507) disclose the use of three-mutually orthogonal accelerometers to determine position and acceleration.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anuradha Roy whose telephone number is (571) 272-6169 and whose email address is anuradha.roy@uspto.gov. The examiner can normally be reached between 8:00am and 4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

~AR~

  
MAX F. HINDENBURG  
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